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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,188	06/05/2000	JAN DROAUD	065691/0184	8841

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FOLEY AND LARDNER

SUITE 500

3000 K STREET NW

WASHINGTON, DC 20007

EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 02/24/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/509,188

Applicant(s)

DROUAUD ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. The amendment filed 12/13/02 has been entered.

Claims 1-10 and 12-18 are pending.

Claims 1, 2, 8, 9, 13, 14, and 16 have been amended.

2. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

3. Rejections and objections not set forth below are withdrawn.

4. Claims 1-10, and 12-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/14/2002. Applicant's arguments of 12/13/02 have been fully considered but they are not persuasive.

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Applicants contend that they have provided ample description in the present application of SEQ ID NO:3, including the functional domains of the sequence (page 6 of the response, lines 1-2). Applicants reiterate that by disclosing SEQ ID NO:3, they have disclosed the "most valuable part, i.e., the promoter region" (page 6, 1<sup>st</sup> full paragraph). Applicants contend that there is not a requirement that they provide the exact "domain" [sic] parameters that render the promoter functional (page 6, 2<sup>nd</sup> paragraph). Applicant states that bases 1 to 2056 of SEQ ID NO:3 were used to direct expression specifically in the microspores.

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The Examiner agrees that Applicants disclose bases 1 to 2056 of SEQ ID NO:3. The disclosure of bases 1 to 2056 satisfies the Written Description requirement only for claims drawn to bases 1 to 2056 of SEQ ID NO:3. For any claims drawn to anything less than the full sequence, the before mentioned disclosure does not adequately describe Applicants' invention. Without specifically identifying and describing the functional domains of the promoter, one skilled in the art would not be able to identify sequences exhibiting 80% sequence identity or fragments of SEQ ID NO:3 that still possessed the necessary domains to direct expression of a heterologous gene with the same spatial and temporal expression as bases 1 to 2056 of SEQ ID NO:3.

Applicant contends that they do not have to describe a gene encoding a male-gamete-specific cytotoxic product and also a subtilisin protease because the present invention does not relate to a "male-gamete-specific cytotoxic product. Applicants continue by stating "It is not necessary for applicants to list in the specification each and every protease that may be operably linked to their microspore-specific promoter" (page 7, 3<sup>rd</sup> full paragraph).

The Examiner asserts, that for purposes of satisfying the Written Description requirement, Applicant is required to disclose the genotype and phenotype of plants that Applicant is claiming. For example, claims 5, 6, 7, 12, 14, 15, and 17 are drawn to plants or seeds of a plant transformed with a construct encoding a cytotoxic product. Applicant is claiming plant material but Applicant hasn't disclosed the genotype of the claimed plant. There are many compounds that are "cytotoxic", while the availability of genes encoding them are unclear, and Applicant is not in possession of the claimed material.

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5. Claims 1-10, and 12-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/14/2002. Applicant's arguments of 12/13/02 have been fully considered but they are not persuasive.

Applicants argue that the function of proteases is to degrade, cut and generally catalyze the breakdown of proteinaceous molecules (page 8, 1<sup>st</sup> paragraph). Applicants believe that they have taught that operably linking a gene encoding a protease or subtilisin will disrupt the normal development of the microspore. Applicants also contend that they do not have to provide experimental results for all permutations of their invention (page 8, 2<sup>nd</sup> paragraph). They believe that it is sufficient that they teach that one may use the promoter region of a gene that is specifically expressed in the microspore to drive expression of a cytotoxic product (*ibid*). In addition, given the above information, Applicants further believe that one skilled in the art would be able to obtain, select or design a nucleotide sequence from SEQ ID NO:3 that is 80% homologous and that is capable of expressing a second sequence in microspores.

The Examiner asserts that as stated in the previous office action, it is unclear how expressing a protein which is already present in the microsporocytes to begin with will have an adverse effect on the developmental biology of the microsporocyte. Therefore, given the lack of experimental data which demonstrates that expressing subtilisin in the microspores will create male sterile pollen, the Examiner maintains the assertion that the invention is not enabled because subtilisin is already present in the microspores, as stated in the previous office action. In

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addition, the Examiner is aware what the function of proteases are. But, just because you express them in cells of the microspore does not mean that the microspores will become non-viable. To kill cells is not a simple process as demonstrated by the huge amount of investment companies pour into research trying to find chemical or compositions that can be used as effective herbicides. Applicant has not taught to where the protease is targeted and which biological processes will be disrupted. All Applicant has shown is that they possess a promoter that expresses in microspores. The Examiner further reiterates from the previous office action that without information outlining or disclosing the functional domains of the promoter, a skilled artisan is unable to design a promoter fragment of SEQ ID NO:3 that exhibits 80% sequence identity to SEQ ID NO:3 and still maintains the same activity as SEQ ID NO:3 without undue experimentation. Applicants' assertions are insufficient to overcome the evidence of unpredictability as set forth in the references cited previously

Applicant contends that applying an insecticide to a transformed plant will inhibit the cytotoxic product. Applicant states "this molecule (the insecticide molecule) is capable of restoring the total fertility of the hemizygous plants by inhibition of subtilisin (page 9, 1<sup>st</sup> paragraph).

The Examiner appreciates Applicants' clarification of the process of inducing male fertility using an insecticide. But, given the problems of chemical absorption through cuticular waxes, Applicant has not taught or presented examples which disclose how one skilled in the art is to achieve the desired effect without undue experimentation, as stated in the previous office action.

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6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/14/2002. Applicant's arguments of 12/13/02 have been fully considered but they are not persuasive.

Applicants contend that they are not interested in using a "cytotoxic product that is specific to plant male gametes. Rather, the promoter region of SEQ ID NO:3 directs the expression of any gene to which it is operably linked to the plant male gametes," (page 9, 2<sup>nd</sup> paragraph of (ii).

The Examiner understands from Applicants' arguments that they are not using a cytotoxic product specific to male gametes. But Claim 7 is still directed towards a "gene encoding a male-gamete-specific cytotoxic product" and as such is still indefinite as it embraces subject matter not intended by Applicant. Deletion of "male-gamete specific" before "cytotoxic", and insertion of the phrase --operably linked to a male-gamete-specific promoter-- after "product" would obviate this rejection.

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7. Claims 1-3, 5-9, and 13-14 remain rejected under 35 U.S.C. 102(e) as being anticipated by Cigan et al (filed Jan. 7, 1995, U.S. Patent Number 5,689,049).

Claims 1 and 2 remain rejected under 35 U.S.C. 102(e) as being anticipated by Sim et al (filed June 7, 1995, U.S. Patent Number 5,993,827).

Claims 1-3, 5-9, 12-17 remain rejected under 35 U.S.C. 102(e) as being anticipated by Mariani et al (U.S. Patent Number 5,689,041, filed February 28, 1995).

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Claim 18 remains rejected under 35 U.S.C. 102(a) as being anticipated by Ballinger et al (1996, Biochemistry 35:13579-13585). All of the rejections are maintained for the reasons of record set forth in the Official action mailed 8/14/2002. Applicant's arguments of 12/13/02 have been fully considered but they are not persuasive. It appears that Applicant has grouped their responses of the four 102's into two responses listed in 'iii' and 'iv' and as such, the Examiner's response shall address all the 102 rejections together.

Applicants contend that Cigan teaches a sporophytic promoter that is active before or during male meiosis and that Applicants' invention deals with a gametophytic promoter. Also, Applicants do not agree that one base pair can constitute a promoter fragment.

The Examiner asserts that Applicants do not claim a gametophytic promoter; rather, they claim a promoter that expresses in a gene that produces a cytotoxic product that produces male sterile plants. Applicants use the word "comprising" which is open terminology and can encompass more than what is being specifically claimed. Because Applicants use open claim language and do not set forth any restrictions in the specification on the interpretation of "fragment", the 102 references read on a fragment, in light of a fragment comprising a single base pair. Given the open claim language and lack of specifically claiming a gametophytic expressing promoter, Cigan et al., Sim et al., Mariani et al and Ballinger et al anticipate the claimed invention.

8. Claims 4 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Mariani et al (filed February 28, 1995) taken with Ramjee et al (1996, Protein Engineering 9:1055-1061). This rejection is maintained for the reasons of record set forth in the Official action mailed



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8/14/2002. Applicant's arguments of 12/13/02 have been fully considered but they are not persuasive.

Applicants contend that the Mariani et al reference does not teach the claimed material for the reasons stated above and accordingly, combined with the Ramjee et al reference does not make obvious the claimed invention.

The Examiner contends that because of the broadly worded claims, the Ramjee et al reference combined with Mariani et al reference make obvious the broadly claimed invention.

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

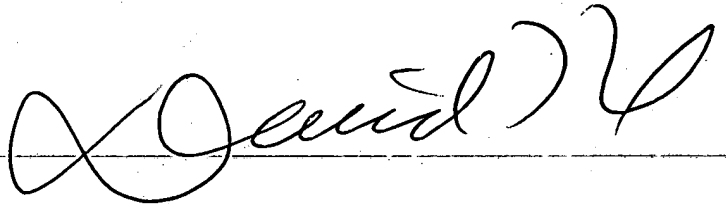
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

February 10, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180/1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over a horizontal line.